

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP2005/002669

## A. CLASSIFICATION OF SUBJECT MATTER

Int.Cl.<sup>7</sup> C07K16/18, G01N33/53, 33/577, C12P21/08

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Int.Cl.<sup>7</sup> C07K16/18, G01N33/53, 33/577, C12P21/08

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

BIOSIS/MEDLINE/WPIDS (STN), WPI (DIALOG), JSTPlus (JOIS), PubMed

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	NINOMIYA, Y. et al., Differential expression of two basement membrane collagen genes, COL4A6 and COL4A5, demonstrated by immunofluorescence staining using peptide-specific monoclonal antibodies., The Journal of Cell Biology., September 1995, Vol.130, No.5, pages 1219 to 1229	1, 2, 4 3
X Y	SUGIHARA, K. et al., Experimental anti-GBM glomerulonephritis induced in rats by immunization with synthetic peptides based on six alpha chains of human type IV collagen., JOURNAL OF PATHOLOGY. March 1996, Vol.178, No.3, pages 352 to 358	1, 2, 4 3

☒ Further documents are listed in the continuation of Box C.☐ See patent family annex.

## \* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;" document member of the same patent family

Date of the actual completion of the international search  
25 May, 2005 (25.05.05)Date of mailing of the international search report  
14 June, 2005 (14.06.05)Name and mailing address of the ISA/  
Japanese Patent Office

Authorized officer

Facsimile No.

Telephone No.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP2005/002669

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	Kazutoshi YOKOYAMA et al., "Type IV Collagen no NC1 Ryoiki (K35) ni yori Yudo sareru Jin'en Model", The Cell, 20 April, 2002 (20.04.02), Vol.34, No.4, pages 36 to 39	1-4
Y	Kazutoshi YOKOYAMA et al., "Nyo to Kessei ni Okeru NC1 (Type IV collagen NC1 Ryoiki) to Ko NC1 Kotai no Sokutei", The Cell, 20 April, 2003 (20.04.03), Vol.35, No.4, pages 40 to 44	1-4

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP2005/002669

**Box No. II** Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 8

because they relate to subject matter not required to be searched by this Authority, namely:

Claim 8 relates to an administration method in constructing an antibody or booster and thus pertains to methods for treatment of the human or animal body by surgery or therapy as well as diagnostic methods to be practiced on the human or animal body. Thus, it relates to (continued to extra sheet)

2. ☐ Claims Nos.:

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III** Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Requirement of unity of invention in the international application is not fulfilled unless there is a technical relationship between the groups of inventions involving one or more of the same or corresponding special technical features (PCT Rule 13.1). The "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art (PCT Rule 13.2). (Continued to extra sheet)

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:  
Claims 1 to 4.**Remark on Protest**

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP2005/002669

Continuation of Box No.II-1 of continuation of first sheet(2)

a subject matter which this International Searching Authority is not required, under the provisions of Article 14(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.

Continuation of Box No.III of continuation of first sheet(2)

Concerning claims, the statement in the description points out that the invention as set forth in claim 6 seems an invention with the use of an anti-NC1 antibody. Thus, the matter common to the inventions as set forth in claims 1 to 6, 9 and 10 resides in "an anti-NC1 antibody". Thus, the matter common to the inventions as set forth in claims 1 to 6, 9 and 10 and the invention as set forth in claim 7 resides in "an antibody against type IV collagen". However, antibodies against type IV collagen had been publicly known prior to the filing of the present international application (see, for example, document 1: NINOMIYA, Y., et al., Differential expression of two basement membrane collagen genes, COL4A6 and COL4A5, demonstrated by immunofluorescence staining using peptide-specific monoclonal antibodies, The Journal of Cell Biology, September 1995, Vol.130, No.5, pages 1219-1229). Thus, "an antibody against type IV collagen" cannot be considered as "a special technical feature".

The matter common to the inventions as set forth in claims 1 to 4 resides in "an anti-NC1 monoclonal antibody immunologically reacting with NC1 in glomerulus" which can be considered as "a special technical feature". Since the matter common to the inventions as set forth in claims 5, 6, 9 and 10 resides in "an anti-NC1 antibody", the matter common to the inventions as set forth in claims 1 to 4 and the inventions as set forth in 5, 6, 9 and 10 resides in "an anti-NC1 antibody" too. However, anti-NC1 antibodies had been publicly known prior to the filing of the present international application too (see, for example, document 1). Thus, it can be concluded that there is no "special technical feature" common to the inventions as set forth in claims 1 to 4 and the inventions as set forth in claims 5, 6, 9 and 10.

Such being the case, claims have the following six invention groups:

- (1) the inventions as set forth in claims 1 to 4;
- (2) the invention as set forth in claim 5;
- (3) the invention as set forth in claim 6;
- (4) the invention as set forth in claim 7;
- (5) the invention as set forth in claim 9; and
- (6) the invention as set forth in claim 10.

A. 発明の属する分野の分類 (国際特許分類 (IPC)) Int.Cl. <sup>7</sup> C07K16/18, G01N33/53, 33/577, C12P21/08		
B. 調査を行った分野 調査を行った最小限資料 (国際特許分類 (IPC)) Int.Cl. <sup>7</sup> C07K16/18, G01N33/53, 33/577, C12P21/08		
最小限資料以外の資料で調査を行った分野に含まれるもの		
国際調査で使用した電子データベース (データベースの名称、調査に使用した用語) BIOSIS/MEDLINE/WPIDS (STN)、WPI (DIALOG)、JSTPlus (JOIS)、PubMed		
C. 関連すると認められる文献		
引用文献の カテゴリー*	引用文献名 及び一部の箇所が関連するときは、その関連する箇所の表示	関連する 請求の範囲の番号
X Y	NINOMIYA, Y., et al., Differential expression of two basement membrane collagen genes, COL4A6 and COL4A5, demonstrated by immunofluorescence staining using peptide-specific monoclonal antibodies., The Journal of Cell Biology. September 1995, Vol. 130, No. 5, pages 1219-1229.	1, 2, 4 3
<input checked="" type="checkbox"/> C欄の続きにも文献が列挙されている。 <input type="checkbox"/> パテントファミリーに関する別紙を参照。		
* 引用文献のカテゴリー 「A」 特に関連のある文献ではなく、一般的技術水準を示すもの 「E」 国際出願日前の出願または特許であるが、国際出願日以後に公表されたもの 「L」 優先権主張に疑義を提起する文献又は他の文献の発行日若しくは他の特別な理由を確立するために引用する文献 (理由を付す) 「O」 口頭による開示、使用、展示等に言及する文献 「P」 国際出願日前で、かつ優先権の主張の基礎となる出願		
の日の後に公表された文献 「T」 国際出願日又は優先日後に公表された文献であって出願と矛盾するものではなく、発明の原理又は理論の理解のために引用するもの 「X」 特に関連のある文献であって、当該文献のみで発明の新規性又は進歩性がないと考えられるもの 「Y」 特に関連のある文献であって、当該文献と他の1以上の文献との、当業者にとって自明である組合せによって進歩性がないと考えられるもの 「&」 同一パテントファミリー文献		
国際調査を完了した日 25. 05. 2005	国際調査報告の発送日 14. 6. 2005	
国際調査機関の名称及びあて先 日本国特許庁 (ISA/J P) 郵便番号100-8915 東京都千代田区霞が関三丁目4番3号	特許庁審査官 (権限のある職員) 上條 肇 電話番号 03-3581-1101 内線 3448	4B 3535

C (続き) . 関連すると認められる文献		
引用文献の カテゴリー*	引用文献名 及び一部の箇所が関連するときは、その関連する箇所の表示	関連する 請求の範囲の番号
X Y	SUGIHARA, K., et al., Experimental anti-GBM glomerulonephritis induced in rats by immunization with synthetic peptides based on six alpha chains of human type IV collagen., JOURNAL OF PATHOLOGY. March 1996, Vol.178, No.3, pages 352-358.	1, 2, 4 3
Y	横山司甫, 他 3 名, タイプIVコラーゲンのNC1領域 (K35) により誘導される腎炎モデル, 細胞, 2002. 04. 20, 第34巻, 第4号, p. 36-39	1-4
Y	横山司甫, 他 1 名, 尿と血清に於けるNC1 (タイプIVコラーゲンNC1領域) と抗NC1抗体の測定, 細胞, 2003. 04. 20, 第35巻, 第4号, p. 40-44	1-4

法第8条第3項（PCT17条(2)(a)）の規定により、この国際調査報告は次の理由により請求の範囲の一部について作成しなかった。

- 様式PCT/ISA/210 (第1ページの続葉 (2)) (2004年1月)

## 第Ⅲ欄の続き

そこで、請求の範囲をみると、請求の範囲6に記載された発明は、明細書中の記載を参酌して、抗NC1抗体を利用した発明と認められるので、請求の範囲1-6、9、10に記載された発明に共通する事項は「抗NC1抗体」である。そうすると、請求の範囲1-6、9、10に記載された発明と請求の範囲7に記載された発明とに共通する事項は「タイプIVコラーゲンに対する抗体」である。しかしながら、タイプIVコラーゲンに対する抗体は、本国際出願時には公知（例えば、文献1：NINOMIYA, Y., et al., Differential expression of two basement membrane collagen genes, COL4A6 and COL4A5, demonstrated by immunofluorescence staining using peptide-specific monoclonal antibodies., The Journal of Cell Biology. September 1995, Vol.130, No.5, pages 1219-1229.）であったから、「タイプIVコラーゲンに対する抗体」は、「特別な技術的特徴」であるとはいえない。

また、請求の範囲1-4に記載された発明に共通する事項は「腎糸球体中のNC1と免疫反応をする抗NC1モノクローナル抗体」であり、これは「特別な技術的特徴」であるといえる。そして、請求の範囲5、6、9、10に記載された発明に共通する事項は「抗NC1抗体」であるから、請求の範囲1-4に記載された発明と請求の範囲5、6、9、10に記載された発明とに共通する事項も「抗NC1抗体」である。しかし、抗NC1抗体についても、本願出願時には公知（例えば、文献1）であったから、請求の範囲1-4に記載された発明と、請求の範囲5、6、9、10に記載された発明との間には、「特別な技術的特徴」は存在しないといえる。

したがって、請求の範囲には、

- ① 請求の範囲1-4に記載された発明、
  - ② 請求の範囲5に記載された発明、
  - ③ 請求の範囲6に記載された発明、
  - ④ 請求の範囲7に記載された発明、
  - ⑤ 請求の範囲9に記載された発明、
  - ⑥ 請求の範囲10に記載された発明、
- の6発明が包含されている。



## 第IV欄 要約 (第1ページの5の続き)

本発明は、抗NC1モノクローナル抗体を用いて、一次性、二次性を問わず腎炎の早期を検出しようとするものである。本発明は、免疫グロブリンが腎糸球体他に沈着の起きない早期の腎生検試料を免疫染色で、又尿や血清などの試料より抗原抗体反応でNC1を見出だす事で腎機能の診断に有用な情報を与えるものである。更に治療に活用するものである。